INSTRUCTION MANUAL
Biometer

Lenstar LS 900®

7. edition / 2014 – 01

HAAG-STREIT DIAGNOSTICS

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INSTRUCTION MANUAL
Biometer

Lenstar LS 900®

7. Edition / 2014 – 01

Introduction

Thank you for choosing a HAAG-STREIT device. Provided you comply carefully with the regulations in these instructions for use, we can guarantee reliable and trouble-free use of our product.

WARNING!
Read the instruction manual carefully before commissioning this product. It contains important information regarding the safety of the user and patient.

NOTE!
Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

Intended use

The LS 900 is a non-invasive, non-contact OLCR (optical low-coherence reflectometry) biometer used for obtaining ocular measurements and performing calculations to assist in the determination of the appropriate power and type of IOL (intraocular lens) for implantation after removal of the natural crystalline lens. The LS 900 measures:

- Axial eye length
- Corneal thickness
- Anterior chamber depth
- Aqueous depth
- Lens thickness
- Corneal curvature
- Radii for flat and steep meridian
- Axis of the flat meridian
- White-to-white distance
- Pupil diameter

Contents

1. Safety 4
1.1 Areas of application of the device 4
1.2 Patient population 4
1.3 Ambient conditions 4
1.4 Shipment and unpacking 4
1.5 Installation warnings 4
1.6 Operation, environment 4
1.6.1 Plausibility of the measurements 5
1.6.2 IOL calculation 6
1.6.3 References 6
1.6.4 IOL constants 6
1.6.5 IOL constants derived using data from an immersion ultrasound biometer 7
1.6.6 IOL constants derived from data from a contact ultrasound biometer 7
1.7 Optical radiation 7
1.8 Disinfection 7
1.9 Warranty and product liability 7
1.10 Symbols 7

2. Introduction 8
2.1 Basic construction 8
2.2 Examination components (LS 900) 8
2.3 Control component (PC) 9
2.4 Instrument table (option) 9

3. Appliance assembly / installation 9
3.1 Safe system configuration according to EN 60601-1 9
3.2 Instrument table (option) assembly 10
3.2.1 Mounting the roller rails/slide plate 10
3.2.2 Mounting the sticker for automatic position recognition 11
3.3 Transporting the device 11
3.3.1 Device connection, cables under the device 11
3.3.2 Device connection, cables at side (option) 12
3.4 Computer connection 12
3.5 Installing a short forehead band when using the optional T-Cone 12

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01-IFU_LS900-7220055-04070_eng.indd 2 09.04.2014 09:47:31

4. Operation 12
4.1 Position of patient during measurement 12
4.2 Measuring with the optional T-Cone 13
4.2.1 Fitting the optional T-Cone 13
4.2.2 Measuring with the T-Cone 13
4.2.3 Removing the optional T-Cone 14
4.3 Fixation 14
4.4 Measured variables 14
4.4.1 A-Scan 14
4.4.2 Keratometry 14
4.4.3 White-to-white distance 14
4.4.4 Pupillometry & visual axis 14

5. Commissioning 15
5.1 Switching on the device 15
5.2 Switching off the device 15

6. Technical data 15
6.1 Power supply 15
6.1.1 Primary side 15
6.1.2 Secondary side 15
6.2 Illumination modalities 15
6.2.1 Eye length measurement (A-Scan) and central fixation 15
6.2.2 Keratometry 15
6.2.3 Illumination 15
6.2.4 Positioning aid (from serial number 2000) 15
6.3 Measured variables Lenstar LS 900 15
6.3.1 Central corneal thickness (CCT) 15
6.3.2 Anterior chamber depth (ACD) 15
6.3.3 Lens thickness (LT) 15
6.3.4 Axial length (AL) 15
6.3.5 Keratometry (R) 16
6.3.6 White-to-white distance (WTW) 16
6.3.7 Pupillometry 16
6.3.8 Study design 16
6.4 Technical data of T-Cone (option) 17
6.4.1 Normative considerations 17
6.4.2 Measuring accuracy 17
6.4.3 Reproducibility 17

7. Software / Help menu / Error messages 17

8. Maintenance 17
8.1 Function check / zero adjustment 18
8.2 Cleaning 18
8.3 Maintenance of T-Cone (option) 18

A. Appendix 18
A.1 Accessories / spare parts 18
A1.1 LENSTAR LS 900 18
A1.2 T-Cone (option) 18

B. Legal regulations 18

C. Classification 19
C.1 LENSTAR LS 900 biometer 19
C.2 T-Cone (option) 19

D. Disposal 19

E. Standards 19

F. EMC supplement 20
F.1 General 20
F.2 Emitted interference (standard table 1) 20
F.3 Immunity (standard table 2) 21
F.4 Immunity on non-life support devices (standard table 4) 22
F.4 Safe distances on non-life support devices (standard table 6) 23

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01-IFU_LS900-7220055-04070_eng.indd 3 09.04.2014 09:47:31

1. Safety

DANGER!
Failure to comply with these instructions may result in material damage or pose a danger to patients or users.

WARNING!
These warnings must absolutely be complied with to guarantee safe operation of the device and to avoid any danger to users and to patients.

NOTE!
Important information: please read carefully.

1.1 Areas of application of the device

The device is intended for use in doctor's practices, hospitals, optometrists' and opticians' premises.

1.2 Patient population

The patient must be capable of sitting up straight and keeping his head still. He must be physically and mentally able to cooperate well and mentally capable of following the examination. Patients must be at least 6 years old.

1.3 Ambient conditions

Transport:	Temperature	from	−40°C	to	+70°C
	Air pressure	from	500 hPa	to	1060 hPa
	Relative humidity	from	10%	to	95%
Storage:	Temperature	from	−10°C	to	+55°C
	Air pressure	from	700 hPa	to	1060 hPa
	Relative humidity	from	10%	to	95%
Use:	Temperature	from	+10°C	to	+35°C
	Air pressure	from	800 hPa	to	1060 hPa
	Relative humidity	from	30%	to	90%

1.4 Shipment and unpacking

- Before unpacking the device, check whether the packaging shows traces of improper handling or damage. If this is the case, notify the transport company that delivered the goods to you.
- Unpack the equipment together with a representative of the transport company. Make a report of any damaged parts. This report must be signed by you and by the representative of the transport company.
- Leave the device in the packaging for a few hours before unpacking it (condensation).
- Check the device for damage after it is unpacked.
- Return defective devices in the appropriate packaging.
- Store packaging material carefully, so that it can be used for possible returns or when moving.
- Check that the contents of the packaging correspond to the contents specified on the leaflet included in the packaging.

1.5 Installation warnings

WARNING!
- Only use a HAAG-STREIT approved external medical power supply (EN 60601-1).
- The plug, cable and socket must function perfectly.
- Before carrying out maintenance or cleaning work, the device must always be disconnected from the mains by unplugging the power supply or plug.
- Computers and further ancillary devices (printers, etc.) must comply with the EN 60601-1 standard, or be connected with galvanic isolation to external networks (isolating transformer, galvanic Ethernet isolator, etc.), see also "Safe system configuration in accordance with EN 60601-1".
- For connection to PC, use only the supplied USB cable (2 m).
- The power supply must be positioned in such a way that proper heat dispersion is guaranteed.

1.6 Operation, environment

DANGER!
- It is expressly forbidden to open the device!
- Never use the device in potentially explosive environments where volatile solvents (alcohol, benzine, etc.) and combustible anaesthetics are in use.

WARNING!
- The doctor or the operator is under an obligation to inform the patient about safety instructions concerning them and to ensure that these instructions are complied with.
- Only staff trained and experienced in the assessment of measuring data and calculations and the manual entry, editing and deletion of data may examine patients, operate the device and interpret results.
- All users must be appropriately trained and familiarised with the contents of the instructions for use, especially with regard to the safety instructions contained therein.
- Measurements can be carried out with dilated or undilated pupils. Dilation of the pupil only influences pupillometry.

01-IFU_LS900-7220055-04070_eng.indd 4 09.04.2014 09:47:31

- We recommend checking the calibration of the optional T-Cone when fitting it and repeating this if necessary (see section "Function check").

NOTE!

- This device may only be used for the purpose described in these instructions for use.
- Installation only by trained specialists.
- The PC on which the EyeSuite software is installed may not contain any other software which could restrict the correct operation of EyeSuite.
- Please switch the computer off if it is not to be used for a long time.
- The device may not be transported, stored or operated outside the specified ambient conditions (see section "Ambient conditions").
- The device is to be used in a room in the medical area with attenuated light.
- If exposed to the effects of an external force (e.g., by being accidentally knocked or dropped), this sensitive measuring device must be promptly checked according to section "Function check" and, if necessary, returned to the factory for repair.
- If the device is moved/transported, a functional check must be performed in accordance with section "Function check".
- Perform a zero adjustment and function check when prompted by the software.
- The selected measuring mode must be checked before every measurement.
- Keep these instructions for use in a place where they are accessible at all times to those working with the device.
- Warranty claims can only be made if the instructions for use have been complied with.
- The manufacturer of the device is not liable for loss or damage due to unauthorised handling of the same. All warranty claims arising in this case are null and void.
- Always remove the dust cover before switching the device on. The light sources can be destroyed by overheating. Likewise, make sure that the device is switched off before attaching the dust cover.
- Repairs may only be conducted by suitably trained and authorised specialist personnel. Incorrect repairs can pose considerable risks for operating staff and patients.
- Only original spare parts and original accessories may be used for repairs.
- The software must be installed by trained personnel.

- The optional T-Cone may only be used with the Lenstar.
- The optional T-Cone may only be used with Lenstar devices with a serial number of ≥ 2000 or Lenstar devices converted to white light illumination.
- The optional T-Cone must be checked for damage before use.
- The optional T-Cone must not be exposed to strong direct sunlight.

1.6.1 Plausibility of the measurements

WARNING!

- Users must check measurement readings for plausibility. This includes the checking of the A-scan and the cursors, which automatically adjust to the signal, the keratometry values, the white-to-white distance and the pupillometry, whenever one of the measurements displays an unusually high standard deviation. The operator must also take into account the type (e.g., posterior subcapsular cataract) and density of the cataract when evaluating plausibility.
- Prior to the measurement, the user must verify that the patient is not wearing contact lenses. Wearing contact lenses will result in erroneous measuring results.
- It may not be possible, under certain circumstances, to carry out measurements on persons with fixation problems.
- In cases of thick cataracts and uncertain measurement of the axial length, ultrasound biometry should be performed as a control examination.
- Dense lenticular opacities may make it impossible to measure the axial eye length and lens thickness.
- Pronounced opacities of the central cornea can likewise make it impossible to measure corneal thickness, anterior chamber depth, lens thickness or axial eye length.
- Blood in the vitreous may make it impossible to measure the axial eye length.
- Keratometry may be erroneous in eyes that have undergone keratorefractive surgery because such eyes may significantly deviate from spherical surfaces.
- The user should make a visual check when carrying out the measurement procedure, to ensure that all light spots are present.
- If the device repeatedly generates error messages, stop using it and contact the customer service.
- You are recommended always to examine both of the patient's eyes five times. The user should subject the measurement readings to extra scrutiny if there is a notable difference between the right and left eye. The following are classed as notable differences:

01-IFU_LS900-7220055-04070_eng.indd 5 09.04.2014 09:47:32

- More than 1 D with respect to central corneal refractive power => 0.18 mm difference with respect to the corneal curvature radius
- More than 0.3 mm with respect to axial eye length
- More than 1 D with respect to emmetropic IOL refractive power

- The user must check the A-Scan when measuring anterior chamber depth in pseudophakic mode. If only one IOL signal is visible, it is not clear whether this signal relates to the front or back of the IOL. Uncertainty in this case can lead to the displayed reading for anterior chamber depth being inaccurate by the thickness of the IOL (approx. ±1 mm).
- The measured corneal thickness is not intended as a basis for the correction of intraocular pressure readings for diagnosing glaucoma.
- An excessively tilted or decentered IOL may make it impossible to measure the anterior chamber depth, lens thickness and aqueous depth.
- Measurement readings obtained from patients with a non-intact cornea (e.g., due to a corneal transplant, corneal opacity or corneal scarring, etc.) may possibly be inaccurate (this applies to keratometry in particular), and the user should check the data for plausibility.
- Ambient light has a bearing on pupil-diameter measurement readings. The user is responsible for ensuring the correct level of ambient light when carrying out pupillometry. The LS 900 cannot monitor ambient light, so do not use pupillometry as the decisive factor when considering keratorefractive surgery.
- Keratometry may not be accurate in eyes with keratoconus, and so the user must verify its plausibility.
- The user must verify that the eye assignment (OD, OS) is correct for the measured eye.
- The white-to-white distance reading is merely an indirect measurement of the inner lateral dimensions of the anterior ocular section. It therefore provides only approximate indications of the actual inner lateral dimensions of the anterior ocular section and of the size of the implant used.
- The measured results of patients with asteroid hyalosis may not be accurate (in particular the axial length measurement) and must therefore be verified by the user in terms of their plausibility.
- If the optional T-Cone is used, the user should verify the even illumination of the cone.

1.6.2 IOL calculation

The measurements taken with the LS 900 are a central element of every IOL calculation. A further important parameter in calculating the lens to be implanted is the IOL constant. When using the Lenstar LS 900, only IOL constants optimised for optical biometers should be used. Please contact your IOL manufacturer for information on optimised IOL constants for optical biometry. An alternative source of information for IOL constants optimised for optical biometry is the website of the “User Group for Laser Interference Biometry” (ULIB) at the University of Wuerzburg, Germany. Even though the constants published there have been optimised for a different optical biometer, published data [1, 2, 3] indicate that these IOL constants can also be used for calculating IOL power with the Lenstar. Downloadable IOL Constants files for the Lenstar, featuring the ULIB IOL-Constants for the Haigis, Hoffer Q, Halladay I, SRK/T and SRK II - Formulae as well as IOL Constants for the use with the Olsen Formula are available in the Key-User section of the Haag-Streit homepage.
To further improve the clinical result, HAAG-STREIT recommends that every surgeon creates personally optimised IOL constants based on pre-operative measurement data generated with the Lenstar and reliable postoperative data (e.g., 3 months after the operation).

1.6.3 References

[1] Buckhurst P J, Wolffsohn J S, Shah S, Naroo S A, Davies L N, Berrow E J, “A new optical low coherence reflectometry device for ocular biometry in cataract patients”, British Journal of Ophthalmology 2009;93:949-953 [2] Holzer M P, Mamusa M, Auffarth G U, “Accuracy of a new partial coherence interferometry analyser for biometric measurements”, British Journal of Ophthalmology 2009;93: 807-810
[3] Rohrer K, Frueh B E, Wälti R, Clemetson I A, Tappeiner C, Goldblum D, “Comparison and Evaluation of Ocular Biometry Using a New Noncontact Optical Low-Coherence Reflectometer”, Ophthalmology 2009, 116:2087-2092

1.6.4 IOL constants

HAAG-STREIT recommends using personalised IOL constants to achieve maximum prediction accuracy of the IOL calculation. Using personalised IOL constants minimises the effects of individual surgical techniques, individual measurement and surgical equipment and individual physiological differences in the patient cohort under treatment on the IOL calculation.

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01-IFU_LS900-7220055-04070_eng.indd 6 09.04.2014 09:47:32

1.6.5 IOL constants derived using data from an immersion ultrasound biometer

If there are optimised IOL constants available from an immersion ultrasound biometer, they may be used as a starting point for further optimisation of IOL calculation with the Lenstar. Differences in IOL calculation may still occur, as the keratometry data are collected in different ways. The “User Group for Laser Interference Biometry” (ULIB) at the University of Würzburg, Germany has published on its website a manual explaining how to correct the effect of keratometry on the IOL constants. Still, the IOL constants acquired in this way should only be used as a starting point for further optimisation/personalisation.

1.6.6 IOL constants derived from data from a contact ultrasound biometer

If there are optimised IOL constants available based on data from a contact ultrasound biometer, they must be stringently recalculated for use with the Lenstar. The “User Group for Laser Interference Biometry” (ULIB) at the University of Würzburg, Germany has published on its website a manual explaining how to correct the effect of ultrasound biometry and keratometry on the IOL constants. Constants acquired in such a way should only be used as a starting point for further optimisation/personalisation.

1.7 Optical radiation

WARNING!
The light from this device may be dangerous. The risk of eye damage increases with the irradiation period. An exposure time with this device at maximum intensity of over 100 individual measurements per patient eye with dilated pupil per day exceeds the risk guideline value.

NOTE!
In accordance with EN 60825-1, the limiting values for class 1 lasers are respected when the device is used in the defined manner.

NOTE!
The device complies with the limit values for risk group 1 in accordance with EN 62471 insofar as no more than 100 individual measurements are performed per day and per patient’s eye with dilated pupil. If this limit value of 100 individual measurements is exceeded, the patient’s eye may be damaged by the white illumination. (Radiance 1800 $Wm^{-2}sr^{-1}$)

1.8 Disinfection

NOTE!
- The device does not need to be disinfected.
- If the optional T-Cone is used, its tip must be cleaned with max. 70% alcohol after each patient.

For more information on cleaning, please refer to the ‘Maintenance’ section.

1.9 Warranty and product liability

- Haag-Streit products must be used only for the purposes and in the manner described in the documents distributed with the product.
- The product must be treated as described in the ‘Safety’ chapter. Improper handling can damage the product. This would void all guarantee claims.
- Continued use of a product damaged by incorrect handling may lead to personal injury. In such a case, the manufacturer will not accept any liability.
- Haag-Streit does not grant any warranties, either expressed or implied, including implied warranties of merchantability or fitness for a particular use.
- Haag-Streit expressly disclaims liability for incidental or consequential damage resulting from the use of the product.
- This product is covered by a limited warranty granted by your seller.
- The optional T-Cone must be stored in its original dust cover and protected from direct sunlight.

For USA only:
- This product is covered by a limited warranty, which may be reviewed at www.haag-streit-usa.com.

1.10 Symbols

Read the instructions for use attentively	General warning: Read the accompanying documentation
Test symbol of CSA with approval for USA	Notes on disposal, see the 'Disposal' chapter
European certificate of conformity	Manufacturer
Year of production	Direct current

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~ Alternating current	REF HS reference number
SN Serial number	IP20 Housing protection
HS Trademark of the manufacturer HAAG-STREIT AG	

2. Introduction

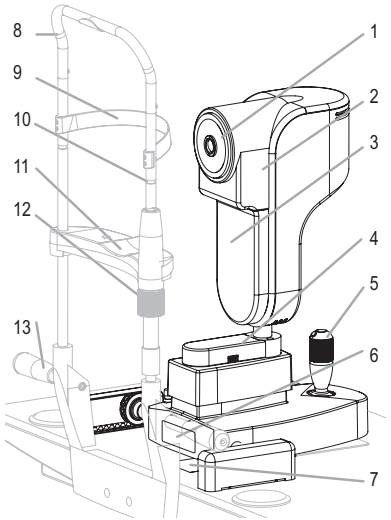
2.1 Basic construction

The system is divided into two parts: one concerned with examination (LS 900) and the other with control (Notebook, PC). The examination part communicates via a USB connection with the external PC. The LS 900 is operated using the "EyeSuite" software installed on the PC. Integral, automatic error recognition for measurements guarantees reliable examination results.

2.2 Examination components (LS 900)

Overview

1. Front ring
2. Housing
3. Service cover
4. Cable cover
5. Control lever
6. Type plate
7. Side identification sticker

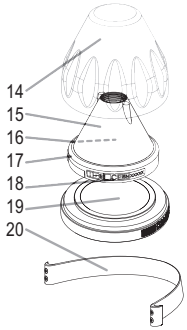


Head rest (option)

8. Head rest
9. Headband
10. Mark for optimum eye height
11. Chin rest
12. Chin rest height adjustment
13. Hand grips for patient

T-Cone (option)

14. Dust cover for storage packaging
15. T-Cone topography add-on
16. "Top" – shows which side of the T-Cone is up.
17. Locking/release clip
18. Type plate
19. Base plate for storage packaging
20. Short forehead band with four Phillips screws



Device state

The device state indicator allows device monitoring without PC software:

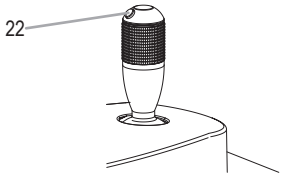
21. State indicator

Dark	Off
Orange	Standby
Green	On
Blue	Light source on
RED	ERROR

Control lever

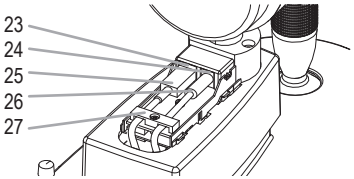
The joystick is used to position the device in relation to the patient's eye.

22. Trigger



Connections

23. USB-device connection
24. DC-device connection
25. USB 2.0 cable
26. DC cable
27. Cable tension compensator



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2.3 Control component (PC)

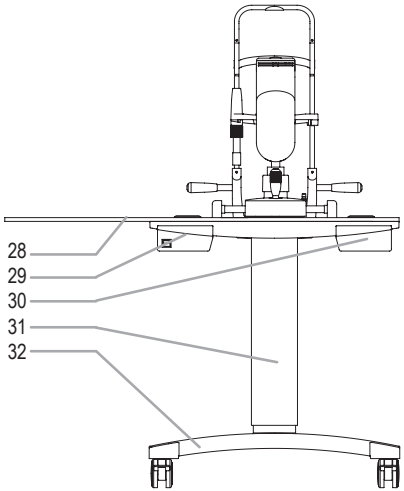
A commercial PC is used as the control component for the biometer.

WARNING!
The software must be installed by trained personnel in accordance with the separate installation instructions. For further information, please contact your HAAG-STREIT representative.

2.4 Instrument table (option)

An adjustable instrument table (option) allows the height of the device to be set at a comfortable height for the individual patient.

28. Table top
29. Left-hand drawer (for external medical power supply) / Switch box SB01
30. Right-hand drawer (empty)
31. Elevator column (mechanical with spring)
32. Stand base with castors



3. Appliance assembly / installation

3.1 Safe system configuration according to EN 60601-1

DANGER!
- It is not permitted to make modifications to the measuring device.

WARNING!
- The device must only be installed on a stable, horizontal surface.
- All externally connected devices must comply with the standards relevant to safety.

NOTE!
- After installation, a zero adjustment and function check must be performed in accordance with the section "Function check".
- The device should be set up in such a way that the plug is always easily accessible and the device can easily be disconnected from the power supply.

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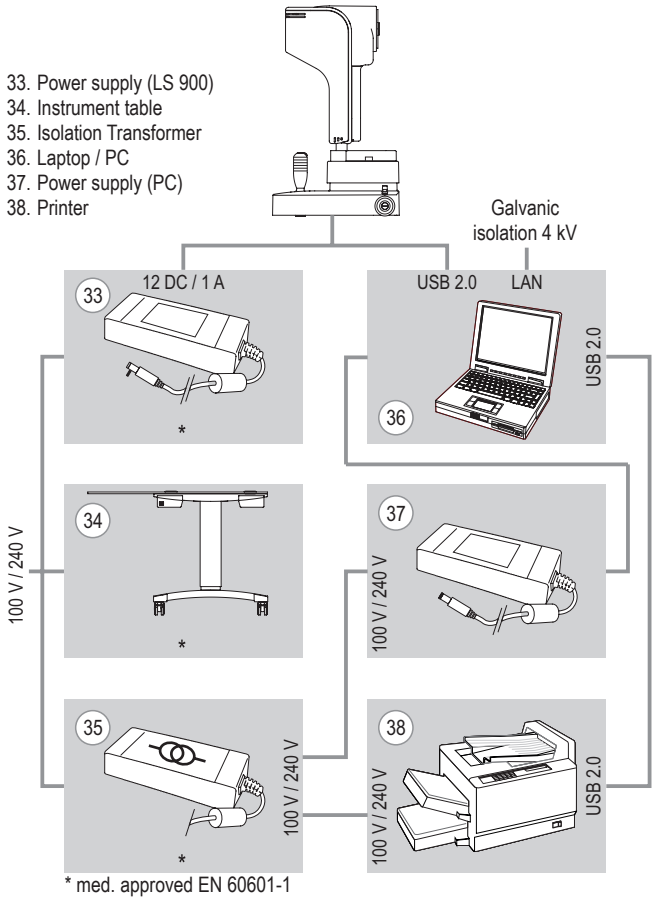
33. Power supply (LS 900)
34. Instrument table
35. Isolation Transformer
36. Laptop / PC
37. Power supply (PC)
38. Printer



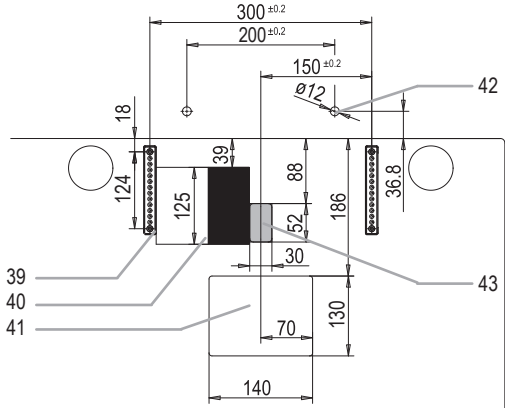
3.2 Instrument table (option) assembly

The instrument table is delivered in a separate package.
To assemble the table, please consult the instructions for use enclosed with it.

3.2.1 Mounting the roller rails/slide plate

The roller rails/slide plate must be positioned in such a way that when the device is centered, the patient's eye will be at a distance of 78 mm from the front of the device.

39. Rail
40. Side identification sticker
41. Slide plate
42. Headrest columns
43. Aperture for cables



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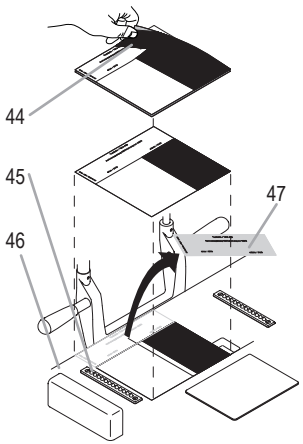
3.2.2 Mounting the sticker for automatic position recognition

- Take off rail cover and move the device to the side, if already in position.
- Clean surface of table.
- Remove protective film (44) from back of the sticker. Start lifting it off carefully from the corner opposite the white area.
- Position the sticker with the white side against the left roller rail (44) and the edge of the table (46). Press the black/ white area down firmly and stroke out any air bubbles.
- Carefully tear off the rest of the sticker (47) (Positioning Tool) along the perforations
- Check whether the position recognition function in the software works correctly.

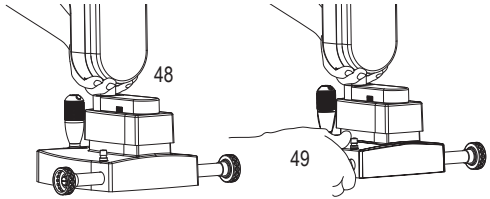


3.3 Transporting the device

Transport the device over longer distances in its original packaging.

WARNING!
In its original packaging, the device can withstand the transport conditions as per EN ISO 15004-1.

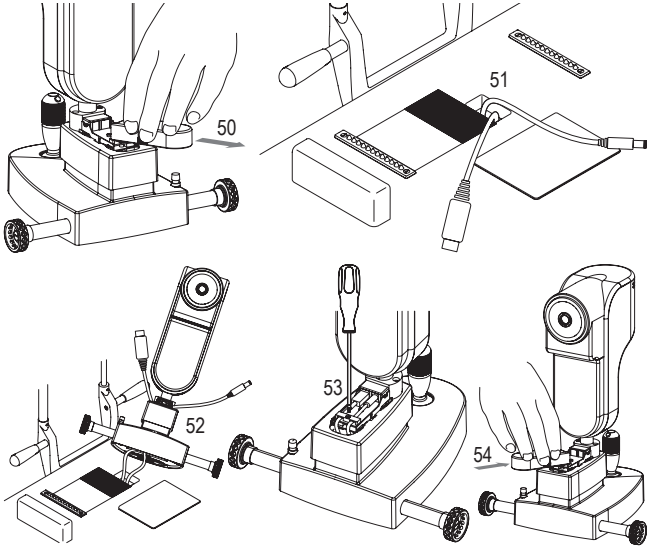
For short distances, grasp the device by the base and lift (48), then support the cross slides with your second hand (49).



3.3.1 Device connection, cables under the device

The device can be invisibly wired by passing cables through the cross slide and using the cable channel underneath. To do this, you need either the HAAG-STREIT instrument table HSM 901 (option) or an aperture in the table-top used.

- Remove cable cover (50).
- Expose USB and supply cables (table aperture, (51)).
- Insert the supply cable through the opening beneath the cross slide until the cable emerges from the opening at the top at the front (52).
- Insert the USB cable through the same opening (52) on the cross slide.
- Insert both cables in the appropriate box and fix with the tension compensator (53).
- Replace the cable cover (54).
- Replace the rail cover.



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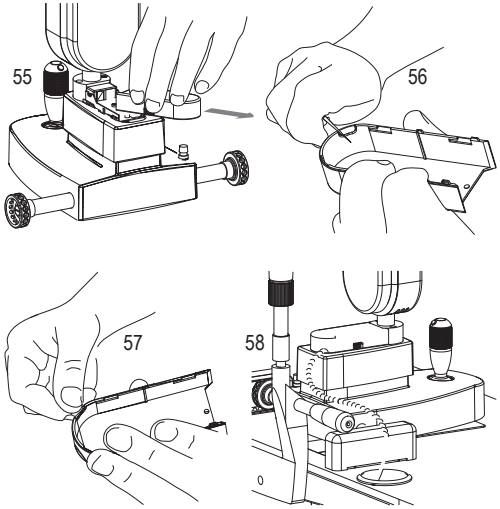
01-IFU_LS900-7220055-04070_eng.indd 11 09.04.2014 09:47:40

3.3.2 Device connection, cables at side (option)

- Remove cable cover (55).
- Expose USB and supply cables (left or right aperture on rail cover).
- With a knife, cut carefully into the snap-off point provided on the left or right of the cable cover (56).
- Carefully use fingers to snap off the cut part (57).
- Insert both cables in the appropriate box and fix with the tension compensator.
- Join both cables together with a spiral wrap and fix in place using the cable channel on the rail cover (58).
- Replace cable cover
- Replace the rail cover.



3.4 Computer connection

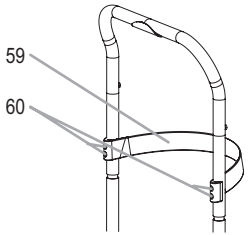
WARNING!
For connection to PC, only use the supplied USB cable (2 m)

- Connect the electric power supply cable. Integral mains components work with the voltages specified under section A.1.1 "Electrical data". It is not necessary to select the voltage on the device.
- If an instrument table HSM 901 (option) has been supplied, the power supply of the LS 900 can be connected to the Switchbox SB01 (left drawer). Use the instructions for use enclosed with the switchbox and the instrument table.

3.5 Installing a short forehead band when using the optional T-Cone

NOTE!
If the Lenstar LS 900 biometer with the optional T-Cone topography add-on is used on an instrument table with a HAAG-STREIT head rest *(HS art. no. 7200123*), the short forehead band delivered with the optional T-Cone must be used on the head rest for better measurability. If the Lenstar is operated without the optional T-Cone, the short forehead band does not need to be replaced with the long one.

- Detach the forehead band by removing the four Phillips screws (60) using a size 1 Phillips screwdriver.
- Remove the forehead band (59).
- Insert the short forehead band (*HS art. no. 1021653)* into the head rest and align the holes with the holes in the head rest.
- Attach the short forehead band using the four Phillips screws supplied.



4. Operation

4.1 Position of patient during measurement

Positioning of the device is done manually by the user. The patient must be positioned in such a way that the distance from the measuring head to the eye is approx. 68 mm. A steady head position is promoted by resting the patient's head in good contact with the chin rest and forehead band, and by the patient holding on to the handles supplied. This can positively influence adjustment time and measuring accuracy. The patient should sit up as straight as possible.

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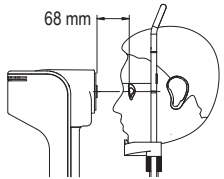
01-IFU_LS900-7220055-04070_eng.indd 12 09.04.2014 09:47:41

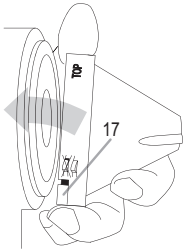


NOTE!
In order to get the best possible results, the patient should be requested to keep the eye as wide open as possible during the measurement and to focus on the measuring beam. Blinking is permitted, but should be kept to a minimum.

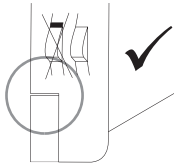
4.2 Measuring with the optional T-Cone

4.2.1 Fitting the optional T-Cone

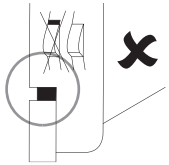
- Remove the dust cover from the storage packaging.
- Hold the T-Cone with the locking clip (17) pressed down next to the metal ring and fit it on the front ring of the Lenstar as shown on the illustration.
- Keep the locking clip depressed so that the T-Cone lies flush with the front ring. Make sure that "TOP" on the metal ring of the T-Cone is at the top. The T-Cone is held in place on the front ring of the Lenstar LS 900 biometer by strong magnets.



- Ensure that the red safety mark is no longer visible on the locking clip. If the red safety mark is still visible, remove the T-Cone and fit it again.



The T-Cone is fitted correctly. The red safety mark is not visible.



The T-Cone is not fitted correctly. The red safety mark is visible. Please remove the T-Cone and fit it again.

WARNING!
- The T-Cone can only be used with the Lenstar with which it was calibrated. To use the T-Cone on another Lenstar or to use another T-Cone on a Lenstar with an already saved T-Cone calibration, the calibration must be performed again.
- The measuring distance from the T-Cone to the eye (apex) is approx. 6 mm. Depending on the anatomy of the patient, the tip of the T-Cone may touch the eyelid or bridge of the nose. To avoid injuries, care must always be taken when moving the Lenstar with fitted T-Cone towards the patient.

NOTE!
- When you use the T-Cone for the first time with the Lenstar LS 900 biometer, the software will prompt you to calibrate the T-Cone with the Lenstar LS 900 biometer. To do so, follow the software wizard and read the software operating instructions (F1 key).
- We recommend performing a test measurement every time the T-Cone is fitted and removed. The test measurement can be invoked in the software's biometry menu. To do so, follow the software wizard and read the software operating instructions (F1 key).

4.2.2 Measuring with the T-Cone

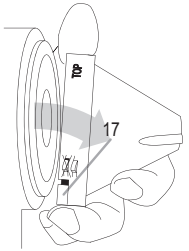
- Fit the T-Cone as described in 4.2.1.
- Prior to every measurement procedure, the tip of the T-Cone should be cleaned with a lint-free cloth soaked in 70% alcohol. To do so, use a moistened cotton bud or lint-free cloth. The cloth or cotton bud must not be so wet that it drips. Ensure that the T-Cone is dry after the cleaning. Information on cleaning the T-Cone can be found under "Cleaning".
- Retract the Lenstar / T-Cone completely before positioning the patient in the head rest. Always start the measuring procedure with the Lenstar / T-Cone in the position furthest away from the patient.
- Explain to the patient that he should focus on the red, flashing light (measuring beam) in the centre of the T-Cone. The second eye (the one not being measured) can be covered with the eye patch on the optional head rest.
- Start the measuring procedure by pressing the button on the joystick and following the instructions on your PC screen. Detailed information on the measuring procedure can be found in the operating instructions for the software (F1 key).

01-IFU_LS900-7220055-04070_eng.indd 13 09.04.2014 09:47:42

NOTE!
Ensure that the Lenstar / T-Cone is in the position furthest away from the patient before switching from the first eye to the second eye. This ensures that the T-Cone will not touch with the bridge of the patient's nose.

4.2.3 Removing the optional T-Cone

- Hold the T-Cone by the metal ring and press the locking clip. Now remove the T-Cone by tilting it off the front ring of the Lenstar as shown in the image.
- Place the T-Cone on the base plate of the storage packaging (19).
- Place the dust cover (14) on the base plate of the storage packaging (19) to protect the T-Cone from dust and dirt.



4.3 Fixation

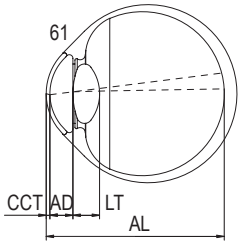
To obtain usable results, the patient must stare at the red fixation light in the measuring lens during measurement. If the patient has difficulty seeing the fixation light with the eye being measured, this can be remedied by fixating a remote object with the other eye.

4.4 Measured variables

4.4.1 A-Scan

Depending on the patient's gaze at the fixation light, the optical path length of the visual axis is measured (61).

CCT: Central corneal thickness
AD: Aqueous depth (back of cornea to front of lens).
LT: Lens thickness
AL: Eye length (front of cornea to the inner limiting membrane).



r

NOTE!
Since the device measures up to the retinal pigmented epithelium, the reading displayed is adjusted to the internal limiting membrane, either automatically, as a function of axial length, or manually, according to the mode selected. (Manual correction is not available in the USA)

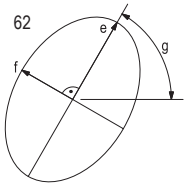
4.4.2 Keratometry

Keratometry is calculated through the position of 32 projected light reflections. Two rings, with sixteen measuring points on each eye are arranged in two rings with the following diameters

(standard eye R=7.8 mm) Outer measuring points: 2.3 mm
Inner measuring points: 1.65 mm

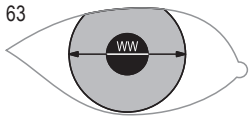
For each measuring point, the equivalent of an ideal sphere is calculated.
The values displayed (flat radius, steep radius) correspond to the radii of an ellipsoid that fits into the array of points. The axis of its rotation is measured counter-clockwise from the horizontal to the flat radius (62).

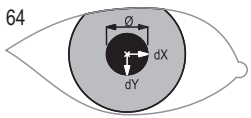
- e: Flat radius
- f: Steep radius
- g: Axis of rotation



4.4.3 White-to-white distance

The white-to-white distance (WTW) is determined using the image of the iris and the eye radii obtained from keratometry. The value displayed corresponds to the diameter of an ideal circle (63).





4.4.4 Pupillometry & visual axis

Pupil diameter (Ø) corresponds to the diameter of an ideal circle, with the smallest error perpendicular to the established pupil border. At the same time, the shift of visual axis towards the centre of the pupil is provided. The calculated dimensions are located on the theoretically derived level of the iris. The image enlargement achieved by the refraction of the eye is disregarded (64).

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01-IFU_LS900-7220055-04070_eng.indd 14 09.04.2014 09:47:42

5. Commissioning

Energy to the Lenstar LS 900 biometer is supplied by the medical power supply FRIWO 3288-DT12/12 HED (*HS no:1020392*).

5.1 Switching on the device

- Connect the power supply up to the mains.
- Switch on the PC.
- Start the software on the PC.

5.2 Switching off the device

- Exit the software on the PC.
- Switch off the PC.
- Disconnect the Lenstar from the mains if you do not intend to use it for an extended period of time.

6. Technical data

Type designation:	LS 900
Dimensions (W x D x H):	310 x 260 x 420 mm
Weight:	6.2 kg

6.1 Power supply

FRIWO 3288-DT12/12 HED	*HS-No: 1020392*

6.1.1 Primary side

Voltage:	100 – 240 V / 50 – 60 Hz
Current:	280 – 140 mA

6.1.2 Secondary side

Voltage:	12 V ⎓
Current:	1 A

6.2 Illumination modalities

6.2.1 Eye length measurement (A-Scan) and central fixation

Light source:	Superluminescent diode
Wavelength:	820 nm
Power on patient's eye:	< 0.6 mW

6.2.2 Keratometry

Light source:	LED
Wavelength:	950 nm

6.2.3 Illumination

	Serial number of the system	
	Up to 1999*	From 2000
Light source:	LED	LED
Light colour:	Green	White

* Devices with a serial number < 1999 can be subsequently converted to white light illumination

6.2.4 Positioning aid (from serial number 2000)

Light source:	LED
Wavelength:	940 nm

6.3 Measured variables Lenstar LS 900

Measurement ranges are based on the 'Phakic' measurement mode.

6.3.1 Central corneal thickness (CCT)

Measurement range:	300 – 800 µm
Display resolution:	1 µm
In vivo repeatability (1.SD):	±2.3 µm

6.3.2 Anterior chamber depth (ACD)

Measurement range:	1.5 – 6.5 mm
Display resolution:	0.01 mm
In vivo repeatability (1.SD):	±0.04 mm

6.3.3 Lens thickness (LT)

Measurement range:	0.5 – 6.5 mm
Display resolution:	0.01 mm
In vivo repeatability (1.SD):	±0.08 mm

6.3.4 Axial length (AL)

Measurement range:	14 – 32 mm
Display resolution:	0.01 mm
In vivo repeatability (1.SD):	±0.035 mm

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01-IFU_LS900-7220055-04070_eng.indd 15 09.04.2014 09:47:43

6.3.5 Keratometry (R)

Measurement range radius:	5 – 10.5 mm
Display resolution:	0.01 mm
In vivo repeatability (1.SD):	±0.03 mm
Measuring area of axial angle:	0 – 180°
Display resolution:	1°
In vivo repeatability (1.SD):	±11°

6.3.6 White-to-white distance (WTW)

Measurement range:	7 – 16 mm
Display resolution:	0.01 mm
In vivo repeatability (1.SD):	±0.04 mm

6.3.7 Pupillometry

Measurement range:	2 – 13 mm
Display resolution:	0.01 mm

The above mentioned measurement ranges correspond to the default setting for the automatic analysis. The in vivo reproducibility was evaluated in a clinical study of cataract patients (see Tables 1 "All eyes" and 2 "Special eyes")

6.3.8 Study design

- The clinical trial for deriving in vivo reproducibility was approved by the local ethics committee. The study was planned and conducted as a prospective, non-randomised comparative study.
- Two phases were scheduled in the approved study protocol. In the first phase, measurements of axial length (AL), central corneal thickness (CCT), anterior chamber depth (ACD), central lens thickness (LT), median corneal radius (R) and the axis position of the flat meridian (axis) were taken.
- The white-to-white distance (WTW) was measured in the second phase.
- A total of 144 eyes in 80 subjects were included in study phase 1 and a total of 40 eyes in 20 subjects in study phase 2.
- Subjects with different conditions of the anterior and posterior segment of the eye (cataract in different stages, pseudophakia with different IOLs, aphakia, silicone-oil fill) and subjects with healthy eyes were included in this clinical study. Data were analyzed for all eyes (see Tab. 1) and for a subgroup of eyes with special health conditions (see Tab. 2), with a complete set of 5 repeat measurements on both eyes of each subject.
- The special eyes group included eyes with one or more of the following conditions: pseudophakia, aphakia and silicone-oil fill.

Tab. 1: All Eyes

[unit]	n	$Mean_{grand}$	SD_{repeat}	CV
AL [mm]	45 / 90	23.973	0.035	0.00145
CCT [µm]	53 / 106	557.1	2.3	0.00407
ACD [mm]	34 / 68	3.19	0.04	0.01220
LT [mm]	27 / 54	4.56	0.08	0.01784
R [mm]	34 / 68	7.67	0.03	0.00396
Axis [°]	27 / 54	72	11	0.14191
WTW [mm]	9 / 18	12.27	0.04	0.00337

Tab. 2: Special Eyes

[unit]	n	$Mean_{grand}$	SD_{repeat}	CV
AL [mm]	10 / 20	24.087	0.056	0.00234
CCT [µm]	11 / 22	564.4	2.8	0.00496
ACD [mm]	5 / 10	7.75	0.03	0.00333
Axis [°]	3 / 6	80	13	0.16092

Abbreviations

n	Number of subjects / number of eyes
$Mean_{grand}$	Overall mean of results on all eyes
SD_{repeat}	Repeatability standard deviation
CV	Coefficient of variation

SD	Standard deviation	**LT**	Lens thickness
AL	Axial length	**R**	Corneal radius of curvature
CCT	Central corneal thickness	**Axis**	Axis of flat meridian
ACD	Anterior chamber depth	**WTW**	White-to-white distance

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01-IFU_LS900-7220055-04070_eng.indd 16 09.04.2014 09:47:43

6.4 Technical data of T-Cone (option)

Type designation:	T-Cone
Diameter:	ø 84 mm
Length:	63.5 mm
Weight:	0.2 kg
Placido rings:	11
Covered optical zone:	≤ 6 mm

6.4.1 Normative considerations

- The T-Cone complies with the requirements of the ISO 19980:2012 standard for the central and medial measuring zones; the T-Cone does not cover the peripheral measuring zone.
- International standard for ophthalmological instruments.
- Corneal topographer, type B.
- The T-Cone complies with the requirements of the ANSI Z80.23-2012 standard for the central and medial measuring zones; the T-Cone does not cover the peripheral measuring zone.
- US national standard for ophthalmological instruments
  Corneal topography system, type B.

6.4.2 Measuring accuracy

Test surface (axial curvature difference in mm / elevation difference in µm)

	Central zone (Diameter ≤ 3 mm)			Middle zone (3 < Diameter ≤ 6 mm)		
	Mean value Curvature diff.	2 st. dev. Curvature diff.	2 st. dev. Elevation diff.	Mean value Curvature diff.	2 st. dev. Curvature diff.	2 st. dev. Elevation diff.
Toric (mm), R_1=7.987, R_2=7.584	0.006	0.065	0.66	0.004	0.044	0.33
Ellipsoid (mm), R=7.79, k=−0.255	0.001	0.083	0.78	0.020	0.038	1.51
Sphere 1 (mm), R=6.448	0.013	0.037	0.61	0.012	0.025	1.12
Sphere 2 (mm), R=7.804	−0.008	0.034	0.33	−0.008	0.026	0.75
Sphere 3 (mm), R=8.844	−0.017	0.056	0.46	−0.024	0.038	1.61
Sphere 4 (mm), R=10.501	−0.040	0.082	0.48	−0.069	0.044	0.58

Sphere 1: ø11.5 mm
Toric, ellipsoid, sphere 2,3,4: ø14 mm
All surfaces: Precision ± <1 µm
Test surfaces were centred within ± 0.1 mm and their symmetry axes aligned within ± 0.5° with regard to their measuring axis.

6.4.3 Reproducibility

Human cornea (axial curvature difference, D / elevation difference, µm)

Central Zone (Diameter ≤ 3 mm)			Middle zone (3 < Diameter ≤ 6 mm)		
Mean value	1 st. dev.	2 st. dev.	Mean value	1 st. dev.	2 st. dev.
−0.001 / −	0.38 / 0.66	0.76 / 1.31	−0.020 / −	0.36 / 3.22	0.72 / 6.45

n = 42 eyes

7. Software / Help menu / Error messages

The software's help section contains instructions and help for performing an examination and descriptions of the error messages. The help can be opened via the F1 key or in the [?] – [Help] menu.

WARNING!
The software must be installed by trained personnel in accordance with the separate installation instructions.

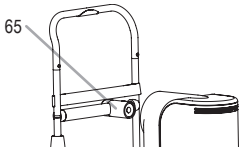
8. Maintenance

The LS 900 is practically maintenance-free and requires only minimum care to work for as long as possible to your complete satisfaction. However, we recommend instructing a service engineer to inspect the biometer periodically. HAAG-STREIT or your local agent will be happy to provide further information.

01-IFU_LS900-7220055-04070_eng.indd 17 09.04.2014 09:47:43

8.1 Function check / zero adjustment

The inspection gauge (65) supplied with the device will assist the user in checking the proper functioning of the unit. The type plate with the serial number can be found on the rear of the gauge. This check takes place for the first time when the device is commissioned. Subsequent test intervals (1 week) will be specified by the software (message displayed). For exact procedure see software instructions for use. Should the test be outside the tolerance limits, a software message appears and the unit must be taken out of use. Notify your HAAG-STREIT customer support center.



8.2 Cleaning

Regular dusting of the device with a soft cloth is sufficient. More stubborn dirt can be removed using a soft, lint-free cloth dampened with water or alcohol at maximum 70%.

WARNING!
- Avoid making the device wet and use only the means listed above. Under no circumstances use solvent or any abrasives.
- The T-Cone must never be immersed in cleaning fluid or disinfectant. No abrasive or otherwise aggressive agents must be used for cleaning/disinfection. Suitable media include water and up to 70% alcohol. Ensure that the T-Cone is dry after every cleaning/disinfection.

A dust cover is included in the accessories of the LS 900. Cover the device when the room is being cleaned or if it is not used for longer periods of time. Always remove the dust cover before switching on the power.

WARNING!
The device must not be switched on when covered! (Heat build-up, fire hazard).

8.3 Maintenance of T-Cone (option)

The optional T-Cone requires practically no maintenance apart from the cleaning of the tip between patients (see Measuring with the T-Cone).

A. Appendix

A.1 Accessories / spare parts

A1.1 LENSTAR LS 900

Component	HS art. no.
T-Cone Toric Platform	*7220397*
EyeSuite IOL Toric Planner	*7220396*
Electric power supply lead CH	*1001319*
USA power supply lead	*1001316*
Dust cover (small)	*1001395*
Checking gauge (replacement)	*1021124*
Head rest (LS 900)	*7200123*
Eye patch	*1400113*
Instrument table HSM 901 Workstation, manual	*7220085*
Instrument table HSM 901 Workstation, electric lifting column 230 V	*7220149*

A1.2 T-Cone (option)

Component	HS art. no.
T-Cone (without Toric Planner) only for use with the Eyesuite IOL Toric Planner installed	*7220384*
Dust cover for storage packaging	*1021665*
Base plate for storage packaging	*1021666*
Short forehead band with Phillips screws for forehead band (4 pcs)	*1021653* *1005072*

B. Legal regulations

- HAAG-STREIT maintains a quality management system in accordance with EN ISO 13485. The device has been developed and designed taking into consideration all the standards listed in section E ‘Standards’.
- This is a Class IIa device in accordance with Appendix IX of Directive 93/42/EEC. By affixing the CE mark we confirm that our device complies with the applicable standards and directives.
- You can request a copy of the declaration of conformity for the device from HAAG-STREIT at any time.

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01-IFU_LS900-7220055-04070_eng.indd 18 09.04.2014 09:47:43

C. Classification

C.1 LENSTAR LS 900 biometer

EN 60601-1	Continuous operation
EN 60825-1	Laser class I
EN 60529	Enclosure protection IP20
EN 62471	Risk group 1
EN ISO 15004-2	Group 2
93/42/EEC (medical devices)	Class IIa
FDA	Class II

C.2 T-Cone (option)

ISO 19980:2005	Corneal topograph, type B
ANSI Z80.23-2008	Corneal topograph, type B
93/42EEC (medical devices)	Class I
FDA	Class I

D. Disposal

Electrical and electronic devices must be disposed of separately from household waste! This appliance was made available for sale after the 13th August 2005. For correct disposal, please contact your HAAG-STREIT representative. This will guarantee that no hazardous substances enter the environment and that valuable raw materials are recycled.

E. Standards

EN 60601-1	EN ISO 15004-1
EN 60601-1-2	EN ISO 15004-2
EN 62471	EN ISO 10343
EN 60825-1	EN ISO 22665
EN 60529	ISO 19980
ANSI Z80.23	

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01-IFU_LS900-7220055-04070_eng.indd 19 09.04.2014 09:47:44

F. EMC supplement

F.1 General

The Lenstar LS 900 complies with the standard EN 60601-1-2. The instrument is constructed such that the generation and emission of electromagnetic interference is limited so as not to disrupt the intended use of other devices, while the instrument itself possesses an appropriate immunity to electromagnetic interference.

WARNING!

- Electrical medical devices and systems are subject to special EMC measures and must be installed in accordance with the EMC instructions contained in this accompanying document.
- Portable and mobile HF communication systems may interfere with electrical medical devices.
- The use of cables or equipment other than those listed may lead to a higher emission or to reduced interference immunity of the Lenstar LS 900 biometer system.

F.2 Emitted interference (standard table 1)

Guidance and manufacturer's declaration – electromagnetic emissions

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Emission of harmonics according to EN 61000-3-2	Class A	

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01-IFU_LS900-7220055-04070_eng.indd 20 09.04.2014 09:47:44

F.3 Immunity (standard table 2)

Guidance and manufacturer's declaration – electromagnetic immunity

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Immunity test standard	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered withs ynthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst EN 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV for symmetrical voltages ± 2 kV for asymmetrical voltages	± 1 kV for symmetrical voltages ± 2 kV for asymmetrical voltages	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines EN 61000-4-11	< 5% U_T (> 95% drop in U_T) for ½ cycle < 40% U_T (> 60% drop in U_T) for 5 cycles < 70% U_T (> 30% drop in U_T) for 25 cycles < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for ½ cycle < 40% U_T (> 60% drop in U_T) for 5 cycles < 70% U_T (> 30% drop in U_T) for 25 cycles < 5% U_T (> 95% drop in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued function even in the event of interruptions in the energy supply, this product should be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field EN 61000-4-8	3 A/m	0.3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T= the AC mains voltage prior to application of the test level.

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01-IFU_LS900-7220055-04070_eng.indd 21 09.04.2014 09:47:44

F.4 Immunity on non-life support devices (standard table 4)

Guidance and manufacturer's declaration – electromagnetic immunity

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Electromagnetic environment – guidance

Portable and mobile RF communications equipments hould be used no closer to any part of this product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test standard	EN 60601 test level	Compliance level	Recommended distance[c]:
Conducted RF EN 61000-4-6	3 V_{rms} 150 kHz – 80 MHz	3 V_{rms}	$D = 1.2 \sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz – 2.5 GHz	3 V/m 80 MHz – 800 MHz	$D = 1.2 \sqrt{P}$ 80 MHz – 800 MHz $D = 2.3 \sqrt{P}$ 800 MHz – 2.5 GHz

Where ***P*** is the maximum output power rating of thet ransmitter in watts **(W)** according to the transmitter manufacturer and ***D*** is the recommended separation distance in metres **(m)**. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz the higher frequency applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.
c. Possible shorter distances outside the ISM bands do not contribute to improved application in this table.

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01-IFU_LS900-7220055-04070_eng.indd 22 09.04.2014 09:47:44

F.4 Safe distances on non-life support devices (standard table 6)

Recommended safe distances between portable and mobile HF communication devices and this device.

This product is designed to be operated in an electromagnetic environment in which radiated HF interference is controlled. The customer or user of this product can help to prevent electromagnetic interference by maintaining minimum distances between portable and mobile HF communication systems (transmitters) and this product, as recommended below in accordance with the maximum output of the communication system.

	Safe distance according to transmission frequency (m)		
Nominal output of the transmitter (W)	150 kHz – 80 MHz $D = 1.2\sqrt{P}$	80 MHz – 800 MHz $D = 1.2\sqrt{P}$	800 MHz – 2.5 GHz $D = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a nominal output not listed in the table above, the distance ***D*** can be calculated in meters **(m)** using the equation for the respective column, in which ***P*** is the nominal output of the transmitter in watts **(W)** according to the specifications of the transmitter manufacturer.

NOTE 1:	At 80 MHz and 800 MHz the higher frequency applies.
NOTE 2:	To calculate the recommended safe distance of transmitters in the frequency range of 80 MHz to 2.5 GHz an additional factor of $^{10}/_{3}$ was used to reduce the probability of a mobile/portable communication device causing interference if inadvertently brought into the patient area.
NOTE 3:	These guidelines may not apply in all situations. Electromagnetic wave propagation is influenced by absorption and reflection of buildings, objects and people.

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01-IFU_LS900-7220055-04070_eng.indd 23 09.04.2014 09:47:45

Should you have any further questions, please contact your HAAG-STREIT dealer at:

http://www.haag-streit.com/contact/contact-your-distributor.html

HAAG-STREIT DIAGNOSTICS

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HAAG-STREIT AG
Gartenstadtstrasse 10
3098 Koeniz, Switzerland
Phone +41 31 978 01 11
Fax +41 31 978 02 82
eMail info@haag-streit.com
Internet www.haag-streit.com